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DOCKET NO.: PRES06-00208

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : GENE W. ZDENEK ET AL.

U.S. Serial No. : 09/863,006

Filed : May 22, 2001

For : SCLERAL EXPANSION DEVICE HAVING DUCK BILL

Group No. : 3738

Examiner : William H. Matthews

MAIL STOP AMENDMENT

Commissioner for Patents

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PTO/SB/17 (10-03)

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**FEE TRANSMITTAL
for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 180.00**Complete if Known**

Application Number	09/863,006
Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Examiner Name	William H. Matthews
Art Unit	3738
Attorney Docket No.	PRES06-00208

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Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)				(\$) 0	

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid	
Independent		-20** =		X		=	
Multiple Dependent		-3** =		X		=	

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	86	2201	43	Independent claims in excess of 3	
1203	290	2203	145	Multiple dependent claim, if not paid	
1204	86	2204	43	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)				(\$) 0	

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FEE CALCULATION (continued)**3. ADDITIONAL FEES**

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Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	\$180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

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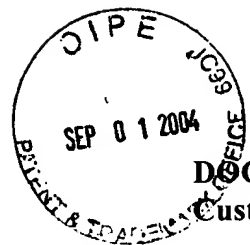
Name (Print/Type)	William A. Munck	Registration No. (Attorney/Agent)	39,308	Telephone	972-628-3600
Signature	<i>William A. Munck</i>	Date	Aug 27, 2004		

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Commissioner for Patents
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Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. § 1.56, Applicant submits this statement. This submittal is made in accordance with 37 C.F.R. §§ 1.97 and 1.98 and § 609 of the Manual of Patent Examining Procedure. The patents and publications herein are listed below and on the attached Forms PTO/SB/08A and PTO/SB/08B. Copies of the cited U.S. and foreign patents are enclosed. Copies of the cited publications can be found in application serial no. 09/650,584.

<u>U.S. Patent No.</u>	<u>Inventor</u>	<u>Date</u>
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4,863,457	Lee	September 5, 1989
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<u>U.S. Patent No.</u>	<u>Inventor</u>	<u>Date</u>
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WO 94/18921	PCT	September 1, 1994
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Applicant hereby expressly reserves the right to swear behind the effective dates of any of the above Patents and to question the relevance and materiality of the Patents and Publications listed herein, in whole, in part, or in combination, subsequent to filing this Information Disclosure Statement.

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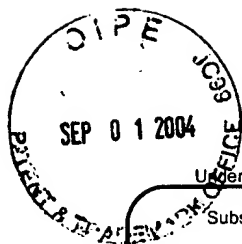
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	09/863,006
Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet 1 of 12

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US- 4,439,198	03/27/1984	Brightman, II et al	
	AB	US- 4,521,210	06/04/1985	Wong	
	AC	US- 4,549,529	10/29/1985	White	
	AD	US- 4,863,457	09/05/1989	Lee	
	AE	US- 5,465,737	11/14/1995	Schachar	
	AF	US- 5,489,299	02/06/1996	Schachar	
	AG	US- 5,503,165	04/02/1996	Schachar	
	AH	US- 5,529,076	06/25/1996	Schachar	
	AI	US- 5,707,643	01/13/1998	Ogura et al.	
	AJ	US- 5,722,952	03/03/1998	Schachar	
	AK	US- 5,731,909	03/24/1998	Schachar	
	AL	US- 5,774,274	06/30/1998	Schachar	
	AM	US- 5,824,086	10/20/1998	Silverstrini	
	AN	US- Re 35,974	12/01/1998	Davenport et al.	
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	AS	US- 5,944,752	08/31/1999	Silverstrini	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	AT	WO 94/18921	09/01/1994			
	AU	WO 00/25703	05/11/2000			
	AV	WO 99/17684	04/15/1999			
	AW	WO 99/17691	04/15/1999			

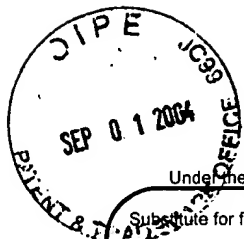
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/863,006
				Filing Date	May 22, 2001
				First Named Inventor	Gene W. Zdenek
				Art Unit	3738
				Examiner Name	W. Matthews
Sheet	3	of	12	Attorney Docket Number	PRES06-00208

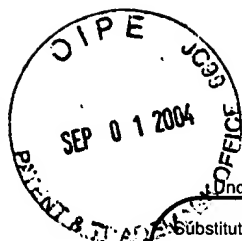
NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Schachar, "Cause and Treatment of Presbyopia With a Method for Increasing the Amplitude of Accommodation," Ann Ophthalmol, 24: 445-452 (1992).	
	CB	Schachar, et al., "Mathematic Proof of Schachar's Hypothesis of Accommodation," Ann Ophthalmol, 25: 5-9 (1993).	
	CC	Schachar, et al., "Experimental Support for Schachar's Hypothesis of Accommodation," Ann Ophthalmol 25: 404-409 (1993).	
	CD	Schachar, et al., "A Physical Model Demonstrating Schachar's Hypothesis of Accommodation," Ann Ophthalmol 26:4-9 (1994).	
	CE	Schachar, "Zonular Function: A New Hypothesis with Clinical Implications," Ann Ophthalmol 26: 36-38 (1994).	
	CF	Schachar, et al., "The Effect of Gravity on the Amplitude of Accommodation," Ann Ophthalmol 26: 65-70 (1994).	
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	CI	Schachar, "Histology of the Ciliary Muscle-Zonular Connections," Ann Ophthalmol 28:70-79 (1996).	
	CJ	Schachar, et al., "Equatorial Diameter During Accommodation," American Physiological Society R670-R676 (1996).	

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				Filing Date	May 22, 2001
				First Named Inventor	Gene W. Zdenek
				Art Unit	3738
				Examiner Name	W. Matthews
Sheet	4	of	12	Attorney Docket Number	PRES06-00208

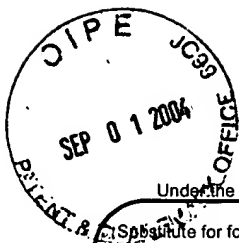
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	DA	Yee, et al., "Scleral Expansion: New Surgical Technique to Correct Presbyopia," Investigative Ophthalmology & Visual Science, Vol. 30(4), 5 (1997).	
	DB	Glasser, et al., "Presbyopia and the Optical Changes in the Human Crystalline Lens with Age," Vision Res., 38:209-229 (1998).	
	DC	Schachar, "Pathophysiology of Accommodation and Presbyopia," J. Florida M.A. 81:268-271 (1994).	
	DD	Schachar, et al., "A Revolutionary Variable Focus Lens," Annals of Ophthalmology, 2811-18 (1996).	
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	DH	Atchison, "Accommodation and Presbyopia," Ophthal Physiol. Opt. 15(4):255-272 (1995)	
	DI	Bernatchez, et al., "Biocompatibility of a new semisolid bioerodable poly(orth ester) intended to the ocular delivery of 5-fluorouracil," J. Biomedical Materials Research, 28:1037-1046 (1994).	
	DJ	Billson, et al., "Resiting Molteno Implant Tubes," Ophthalmic Surgery and Lasers, 27:801-803 (1996).	

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				Application Number	09/863,006
				Filing Date	May 22, 2001
				First Named Inventor	Gene W. Zdenek
				Art Unit	3738
				Examiner Name	W. Matthews
Sheet	5	of	12	Attorney Docket Number	PRES06-00208

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	EA	Brockhurst, "Dystrophic Calcification of Silicone Scleral Buckling Implant Materials," Am. J. Ophthalmol, 115:524-529 (1993).	
	EB	Brouillette, et al., "Long-term results of modified trabeculectomy with Supramid implant for neovascular glaucoma," Can. J. Ophthalmol, 22(5):254-256 (1987).	
	EC	Cameron, et al., "Clinico-histopathologic Correlation of a Successful Glaucoma Pump-shunt Implant," Ophthalmology, 95:1189-1194 (1988).	
	ED	Campbell, et al., "Fluctuations of Accommodation Under Steady Viewing Conditions," J. Physiol., 145:579-594 (1959).	
	EE	Coleman, et al., "Initial Clinical Experience with the Ahmed Glaucoma Implant," Am. J. Ophth. 120:23-31 (1995).	
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	EJ	Daniele, et al., "Gelatin as an Absorbable Implant in Scleral Buckling Procedures," Arch Ophthal, 80:115-119 (1968).	

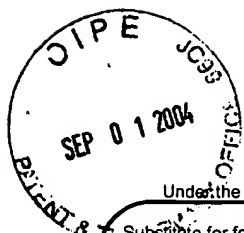
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Application Number	09/863,006		
Filing Date	May 22, 2001		
First Named Inventor	Gene W. Zdenek		
Art Unit	3738		
Examiner Name	W. Matthews		
Attorney Docket Number	PRES06-00208		
Sheet	6	of	12

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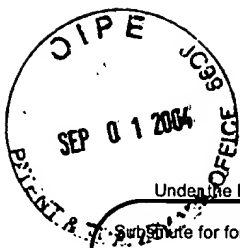
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	FA	Elander, "Scleral Expansion Surgery does not restore accommodatino in human presbyopia," J. Refract. Surg., 15(5):604 (1999).	
	FB	Ellis, "Surgical Conquest of presbyopia; Are There Implications for Cataract and Glaucoma," Refractive Surgery, 38-44 (1999).	
	FC	El-Sayyad, "The Use of Releasable Sutures in Molteno Glaucoma Implants to Reduce Postoperative Hypotony," Ophthalmic Surgery, 22:82-84 (1991).	
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	FF	Hashizoe, et al., "Scleral plug of biodegradable polymers for controlled drug release in the vitreous," Arch. Ophthalmol., 112(10):1380-1384 (1994).	
	FG	Hashizoe, et al., "Biodetgradable polymeric devices for sustained intravitreal release of glanciclovir in rabbits," Current Eye Research, 112(10): 633-339 (1997).	
	FH	Hasty, et al., "Primate Trabeculectomies with 5-fluorouracil Collagen Implants," Am. J. Ophthalmol, 109:721-725 (1990).	
	FI	Hilton, et al., "The Removal of Scleral Buckles," Arch Ophthalmol, 96:2061-2063 (1978).	
	FJ	Ho, et al., "The MAI hydrophilic implant for scleral buckling: a view," Ophthalmic Surg., (6):611-5 (1984).	

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				Application Number	09/863,006
				Filing Date	May 22, 2001
				First Named Inventor	Gene W. Zdenek
				Art Unit	3738
				Examiner Name	W. Matthews
Sheet	7	of	12	Attorney Docket Number	PRES06-00208

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	GA	Jacklin, et al., "Gelatin as an Absorbable Implant in Scleral Buckling Procedure," Arch. Ophthalmol, 79:286-289 (1968).		
	GB	Jacob, et al., "Synthetic scleral reinforcement materials. II Collagen types in the fibrous capsule," J. Biomedical Materials Research, 32:181-186 (1966).		
	GC	Krupin, et al., "Filtering Valve Implant Surgery for Eyes with Neovascular Glaucoma," Am. J. Ophthalmol, 89:338-343 (1980).		
	GD	Krupin, et al., "Long-Term Results of Valve Implants in Filtering Surgery Eyes with Neovascular Glaucoma," Am. J. Ophthalmol, 95:775-782 (1983).		
	GE	Krupin, et al., "A Long Krupin-Denver Valve Implant Attached to a 180 Scleral Explant for Glaucoma Surgery," Ophthalmol, 95:1174-1180 (1988).		
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	GH	Lambert, et al., "Wedge Implant Used as an Explant," Am. J. Ophthalmol., 101:488-489 (1986).		
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	GJ	Law, et al., "Retinal Complications after Aqueous Shunt Surgical Procedures for Glaucoma," Arch Ophthalmol, 114:1473-1480 (1996).		

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Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	8	of	12
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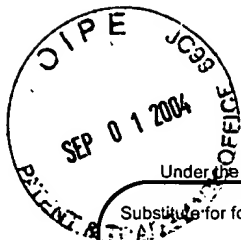
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	HA	Levit, et al., "Use of Ophthalmic Gelfilm in retinal Surgery," Ann. Ophthalmol, 1613-1616 (December 1975).	
	HB	Lipner, "A Closer Look at Scleral Surgery," Eyeworld (September 13, 1999) http://www.eyeworld.org/sep99/999p34.asp	
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	HF	Luttrull, et al., "Pars Plana Implant and Vitrectomy for Treatment of Neovascular Glaucoma," Retina, 15:379-387 (1995).	
	HG	Luttrull, et al., "Initial Experience with Pneumatically Stented baerveldt implant modified for Pars Plana Insertion in Complicated Glaucoma," Ophthalmology, 107:143-149 (2000).	
	HH	Marin, et al., "Long-term Complications of the MAI Hydrogel Intrasceral Buckling Implant," Arch. Ophthalmol, 110:86-88 (1992).	
	HI	Matthews, et al., "Scleral Expansion Surgery Does Not Restore Accommodation in Human Presbyopia, Ophthalmology, 106:873-877 (1999).	
	HJ	Melamed, et al., "Molteno Implant Surgery in Refractory Glaucoma," Survey of Ophthalmology, 34:441-448 (1990).	

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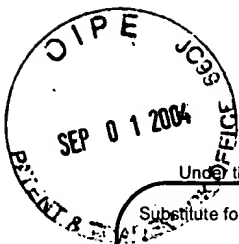
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	IA	Minckler, et al., Clinical Experience with the Single-plate Molteno Implant in Complicated Glaucomas," Ophthalmology 95:1181-1188 (1988).	
	IB	Miyamoto, et al., "Biodegradable Scleral Implant for Controlled Release of Flocanazole," Current Eye Research, 16:930-935 (1997).	
	IC	Ocular Surgery News, "Presbyopia Reversible in Pilot Studies," July 1, 1999; http://www.slackinc.com/eve/osn/199907a/presby.asp	
	ID	Peiffer, et al., "Long-term Comparative Study of the Schochet and Joseph Glaucoma Tube Shunts in Monkeys," Ophthalmic Surgery, 21:55-59 (1990).	
	IE	Pruett, "The Fishmouth Phenomenon," Ach. Ophthalmol, 95:1777-181 (1977).	
	IF	Rabowsky, et al., "The Use of Bioerodeable Polymers and Daunorubicin in Glaucoma Filtration Surgery," Ophthalmology, 103:800-807 (1996).	
	IG	Ray, et al., "Gelatin Implants in Scleral Buckling Procedures," Arch Ophthalmol, 93:799-802 (1975).	
	IH	Refojo, "Polymers in Ophthalmic Surgery," J. Biomed. Mater. Res., 5:113-119 (1971).	
	II	Refojo, et al., "Experimental Scleral Buckling with a Soft Xerogel Implant," Ophthalmic Surgery, 9:43-50 (1978).	
	IJ	Riggs, et al., "Intraocular Silicone Prostheses in a Dog and a Horse with Corneal Lacerations," J. Am. Vet. Med. Assoc., 196:617-619 (1990).	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	09/863,006
Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	10	of	12
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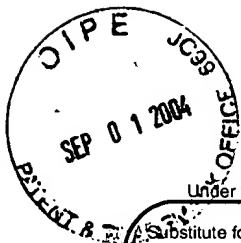
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	JA	Rohr, et al., "Surgical Correction of Presbyopia," J. Osteopathic College of Ophthalmology and Otolaryngology, 12:34-36 (2000).	
	JB	Rubsamen, et al., "Prevention of Experimental Proliferative Vitreoretinopathy with a Biodegradable Intravitreal Implant for the Sustained Release of Fluoroacil," Arch. Ophthalmol. 112:407-413 (1994).	
	JC	Sakamoto, et al., "Silicone Sponge Implant in Combination with Episcleral Implant for Retinal Surgery," Ophthalmic Surgery, 11:712-718 (1980).	
	JD	Sarkies, et al., "Silicone Tube and Gutter in Advanced Glaucoma," Trans. Ophthalmol. Soc. U.K., 144:133-136 (1985).	
	JE	Schepens, et al., "Scleral Implants: An Historic Perspective," Survey of Ophthalmology, 35:447-453 (1991).	
	JF	Sherwood, et al., "Surgery for Refractory Glaucoma," Arch. Ophthalmol, 105:562-569 (1987).	
	JG	Sidoti, et al., "Epithelial Ingrowth and Glaucoma Drainage Implants," Ophthalmol, 101:872-875 (1994).	
	JH	Sidoti, et al., "Aqueous Tube Shunt to a Pre-existing Episcleral Encircling Element in the Treatment of Complicated Glaucomas," Ophthalmol, 101:1036-1043 (1994).	
	JI	Smith, et al., "One-year results of the intrascleral glaucoma implant," J Cataract Refract. Surg., 21:453-456 (1995).	

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				Art Unit	3738
				Examiner Name	W. Matthews
Sheet	11	of	12	Attorney Docket Number	PRES06-00208

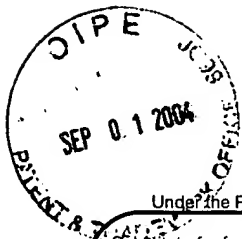
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	KA	Smith, et al., "Comparison of the Double-Plate Molteno Drainage Implant with the Schochet Procedure," Arch. Ophthalmol, 110:1246-1250 (1992).	
	KB	Speigel, et al., "Anterior Chamber Tube Shunt to an Encircling Band (Schochet procedure) in the Treatment of Refractory Glaucoma," Ophthalmic Surgery, 12:804-807 (1992).	
	KC	Strubble, et al., "In vitro low characteristics of the Amhed and self-constructed anterior chamber shunts," Am. J. Vet. Res., 58:1332-1337 (1997).	
	KD	Sveinsson, et al., "Trabeulectomy and gelatin implants," Acta Ophthalmologica, 70:645-650 (1992).	
	KE	Susanna, "Modifications of the Molteno Implants and implant Procedure," Ophthalmic Surgery, 22:611-613 (1991).	
	KF	Szymanski, "Scleral free auto-implant plug with mitomycin as limitation of trepanosclerectomy flow in glaucoma filtering surgery," International Ophthalmology, 20:89-94 (1997).	
	KG	Tanji, et al., "Fascia Lata patch Graft in Glaucoma Tube Surgery," Ophthalmology, 103:1309-1312 (1996).	
	KH	Tawakol, et al., "Gore-Tex Soft Tissue Bands as Scleral Explants in Rabbits: A Preliminary Histologic Study," Ophthalmic Surgery, 20:199-201 (1989).	
	KI	Watzke, "Scleral Patch Graft for Exposed Episcleral Implants," Arch Ophthalmol, 102:114-115 (1984).	
	KJ	Wilson, et al., "New hope for presbyopia: PMMA scleral bands show promise," Eyeworld, (1999); http://www.eyeworld.org/apr98/963.html	

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	LA	Wilson, et al., "Aqueous Shunts - Molteni versus Schocket," Ophthalmology, 99:672-678 (1992).	
	LB	Wilson-Holt, et al., "Hypertrophy flowing insertion of inferiorly sited double-plate Molteno tubes," Eye, (Pt. 5): 515-20 (1992).	
	LC	Yoshizumi, "Exposure of Intrasccleral Implants," Ophthalmology, 87:1150-1154 (1980).	
	LD	Yoshizumi, "Erosion of Implants in Retinal Detachment Surgery," Annals of Ophthalmology, 87:430-434 (1983).	
	LE	Banuelos et al., "Expandable Silicone Implants for Scleral Buckling," Arch Ophthalmol, 89:500-502 (1973).	

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